ALFA WASSERMANN

K063306

510(k) SUMMARY

Alfa Wassermann, Inc. ACE® Hemoglobin A1c Reagent, Hemoglobin A1c Calibrators and Hemoglobin A1c Controls

Submitter

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APR 17 2007

Contact Person

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Date Prepared

October 31, 2006

Product Trade and Common Name

ACE® Hemoglobin A1c (HbA1c) Reagent
Hemoglobin A1c Calibrators
Hemoglobin A1c Controls

Classification Name

Class II, Product Code LCP
CFR § 864.7470: Glycosylated Hemoglobin Assay

Class II, Product Code JIT
CFR § 862.1150: Calibrator, Secondary

Class I, Product Code JJX
CFR § 862.1660: Quality Control Material (assayed and unassayed)

Predicate Devices

Tosoh Bioscience, Inc. A1c 2.2 Plus Automated Glycohemoglobin Assay

General Atomics, Inc. Hemoglobin A1c Enzymatic Assay

Description and Intended Use of the Device

ACE® Hemoglobin A1c (HbA1c) Reagent is intended for the quantitative determination of hemoglobin A1c (µmol/L) and total hemoglobin (g/dL) in human EDTA whole blood for the calculation of percent hemoglobin A1c using the ACE clinical chemistry system. This test is intended for use in clinical laboratories or physician office laboratories to monitor long term blood glucose control in individuals with diabetes mellitus. For in vitro diagnostic use only.

The µmol HbA1c and total hemoglobin (THb) values generated are intended for use in the calculation of the HbA1c/THb ratio and cannot be used individually for diagnostic purposes.

Hemoglobin A1c Calibrators are intended for use in the performance of both a multi-point calibration for hemoglobin A1c and a single-point calibration of total hemoglobin on the ACE clinical chemistry system for the quantitative determination of percent (%) hemoglobin A1c in whole blood. For in vitro diagnostic use only.

Hemoglobin A1c Controls are intended to reliably monitor the accuracy and precision of quantitative determinations of hemoglobin A1c on the ACE clinical chemistry system. For in vitro diagnostic use only.

Technological Characteristics

The ACE Hemoglobin A1c Reagent is provided as a single kit and consists of four bottles containing a hemoglobin denaturant, a total hemoglobin reagent, a HbA1c agglutinator reagent and a HbA1c antibody reagent.

The ACE Hemoglobin A1c Calibrators are provided as a single kit and contain ready-to-use liquid calibrators, one of each of six levels.

The ACE Hemoglobin A1c Controls are provided as a single kit and contain lyophilized controls with normal and elevated levels of HbA1c and a reconstitution fluid. The controls are prepared from human whole blood, which has been tested and found negative for antibody to Human Immunodeficiency Virus (anti-HIV) Types 1 and 2, antibody to Hepatitis C (anti-HCV) and for Hepatitis B Surface Antigen (HBsAg) by FDA recommended (approved/licensed) tests.

Principles of Operation

Prior to assay, whole blood samples require a pretreatment step. The red blood cells in the sample are lysed by the Hemoglobin Denaturant and the hemoglobin chain hydrolyzed.

For determination of HbA1c, a latex agglutination inhibition assay is used. In the absence of HbA1c in the sample, the agglutinator (synthetic polymer containing the immunoreactive portion of HbA1c) in the HbA1c Agglutinator Reagent and the antibody-coated microparticles in the HbA1c Antibody Reagent will agglutinate. The presence of HbA1c in the sample competes for the antibody binding sites and inhibits agglutination. The increase in absorbance, monitored monochromatically at 592 nm on the ACE clinical chemistry system, is inversely proportional to the HbA1c present in the sample.

For the determination of total hemoglobin, all hemoglobin derivatives in the sample are converted to alkaline hematin. The reaction produces a green colored solution, which is measured bichromatically at 573 nm/692 nm on the ACE clinical chemistry system. The intensity of color produced is directly proportional to the total hemoglobin concentration in the sample.

Both the concentration of HbA1c and total hemoglobin are measured; then the ratio is calculated and the result reported as percent HbA1c.

The ACE Hemoglobin A1c Calibrators are used to calibrate the ACE clinical chemistry system for both the Hemoglobin HbA1c and Total Hemoglobin assays.

The ACE Hemoglobin A1c Controls are run in the same way as patient samples.

Performance Data

The performance of the ACE Hemoglobin A1c kit was evaluated for precision, measuring range and accuracy.

The precision studies were done according to CLSI/NCCLS EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition. Using this protocol, precision was measured on the ACE clinical chemistry system using the ACE Hemoglobin A1c reagents, calibrated with the ACE Hemoglobin A1c Calibrators on a normal and elevated patient. The within-run CV for the normal patient was 2.9% and for the elevated patient was 3.0%. The total CV for the normal patient was 7.0% and for the elevated patient was 5.9%.

Further precision studies were done in three separate Physician Office Laboratory (POL) sites. These studies were conducted by personnel without formal medical technology education. The studies consisted of running three EDTA whole blood samples with varying levels of HbA1c in triplicate on five different days. The within-run and total CVs were all less than 5.4%.

The measuring range for total hemoglobin was determined using a whole blood sample, by serial dilution of the packed cells with plasma from the blood sample. HbA1c levels were measured on the ACE clinical chemistry system using the

ACE Hemoglobin A1c reagents, calibrated with the ACE Hemoglobin A1c Calibrators. The acceptable range was determined by using 95% confidence intervals from linear regression analysis with ±10% limits. The acceptable range for total hemoglobin was determined to be 10-21 g/dL.

A correlation study, to determine the accuracy of the ACE Hemoglobin A1c kit, calibrated with the ACE Hemoglobin A1c calibrators, was done against the Tosoh Bioscience's A1c 2.2 Plus Automated Glycohemoglobin Assay. The study followed the protocol in CLSI/NCCLS EP9-T, Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Second Edition. Linear regression analysis was performed: ACE clinical chemistry system (y) and Tosoh HPLC (x). The analysis yielded the following results:

Regression Equation	Correlation Coefficient	Standard Error of the Estimate	Confidence Interval Slope	Confidence Interval Intercept
y = 1.052x+0.23	0.975	0.49	1.000 to 1.104	-0.20 to 0.67

Further accuracy studies were done in three separate POL labs. These studies were conducted by personnel without formal medical technology education. At each lab, these studies consisted of running the same 20 EDTA whole blood samples with varying levels of HbA1c (determined using the Tosoh Bioscience's A1c 2.2 Plus Automated Glycohemoglobin Assay) in duplicate in four different runs of ten samples each. Linear regression analysis was performed: ACE clinical chemistry system (y) and Tosoh HPLC (x). The analysis yielded the following results:

Lab	Regression Equation	Correlation Coefficient	Standard Error of the Estimate	Confidence Interval Slope	Confidence Interval Intercept
A	y = 0.940x+0.41	0.9762	0.46	0.871 to 1.009	-0.16 to 0.99
B	y = 1.102x-0.04	0.9818	0.47	1.032 to 1.172	-0.63 to 0.55
C	y = 1.035x+0.38	0.9844	0.41	0.974 to1.095	-0.89 to 0.13

In all instances, the ACE Hemoglobin A1c kit run on the ACE clinical chemistry analyzer functioned as intended.

Substantial Equivalence

The evaluations and comparative analysis indicated substantial equivalence between the results obtained for the ACE Hemoglobin A1c Reagent, ACE Hemoglobin A1c Calibrators and ACE Hemoglobin A1c Controls and the predicate devices (Tosoh Bioscience's A1c 2.2 Plus Automated Glycohemoglobin Assay and General Atomics Enzymatic HbA1c Assay). The ACE Hemoglobin A1c Reagent, ACE Hemoglobin A1c Calibrators and ACE Hemoglobin A1c Controls have the same intended use and similar indications, technological characteristics, performance characteristics, and similar principles of operation as its predicate devices. Therefore, the ACE Hemoglobin A1c Reagent, ACE Hemoglobin A1c Calibrators and ACE Hemoglobin A1c Controls are substantially equivalent to commercially available products that measure HbA1c in whole blood samples.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Alfa Wassermann Diagnostic Technologies, LLC
c/o Dr. Murray Rosenthal
Manager, Reagent Technology
4 Henderson Drive
West Caldwell, NJ 07006

APR 17 2007

Re: k063306
Trade/Device Name: ACE® Hemoglobin A1c (HbA1c) Reagent
Hemoglobin A1c Calibrators
Hemoglobin A1c Controls

Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated Hemoglobin assay.
Regulatory Class: Class II
Product Code: LCP, JIT, JJX
Dated: March 2, 2007
Received: March 5, 2007

Dear Dr. Rosenthal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Section 4

Section 1.01 Indications for Use Statement

510(k) Number (if known): k063306

Device Name:

ACE® Hemoglobin A1c (HbA1c) Reagent
Hemoglobin A1c Calibrators
Hemoglobin A1c Controls

Indications for Use:

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Hemoglobin A1c Controls are intended to reliably monitor the accuracy and precision of quantitative determinations of hemoglobin A1c on the ACE® clinical chemistry system. For in vitro diagnostic use only.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol C. Benson
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K063306